FACULTY OF PHARMACY
KARPAGAM ACADEMY OF HIGHER EDUCATION

Deemed to be University

(Established Under Section 3 of UGC Act 1956)

Eachanari Post, Pollachi Main Road, Coimbatore – 641021.

M.PHARMACY (PHARMACEUTICAL ANALYSIS)

DEGREE COURSE (2020-2021)

Enable | Enlighten | Enrich

KARPAGAM

ACADEMY OF HIGHER EDUCATION

(Deemed to be University)

(Established Under Section 3 of UGC Act, 1956)

REGULATIONS 2020

COURSE OF STUDY AND SCHEME OF EXAMINATION

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SYLLABUS

CHAPTER – I : REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.)Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)

b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B.Pharm).

3. Duration of the program

The program of study for M.Pharm shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Phamacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

7.1 Credit assignment

7.1.1 Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

7.1.2 Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co- curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical,

Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table V. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester- wise schedule of courses given in the syllabus.

8. Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

9. Course of study

Table I: Course of study for M. Pharm. (Pharmaceutical Analysis)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
20MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
20MPA102T	Advanced Pharmaceutical Analysis	4	4	4	100
20MPA103T	Pharmaceutical Validation	4	4	4	100
20MPA104T	Food Analysis	4	4	4	100
20MPA105P	Pharmaceutical Analysis Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**
Semester II					
20MPA201T	Advanced Instrumental Analysis	4	4	4	100
20MPA202T	Modern Bio-Analytical Techniques	4	4	4	100
20MPA203T	Quality Control and Quality Assurance	4	4	4	100
20MPA204T	Herbal and Cosmetic Analysis	4	4	4	100
20MPA205P	Pharmaceutical Analysis Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Table II: Course of study for M. Pharm III Semester (Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
20MRM301T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
Total		**35**	**21**

*** Non University Exam**

Table III: Course of study for M. Pharm IV Semester (Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
-	Journal club	1	1
-	Research Work	31	16
-	Discussion/Final Presentation	3	3
	Total	**35**	**21**

Table IV: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

*Credit Points for Co-curricular Activities

Table V: GuidelinesforAwardingCredit Points for Co-curricularActivities

Name of theActivity	Maximum Credit Points Eligible / Activity
Participation in National Level Seminar/Conference/Workshop/Symposium/Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/Conference/Workshop/Symposium/Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

Note: International Conference: Held outside India International Journal: The Editorial Board outside India

* The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

10. Program Committee

1. The M. Pharm programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:
   A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

3. Duties of the Programme Committee:

i. Periodically reviewing the progress of the classes.

ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.

iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.

iv. Communicating its recommendation to the Head of the institution on academic matters.

v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table – XVII.

11.1 End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the respective university except for the subject with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Schemes for Internal Assessments and End Semester Examinations (Pharmaceutical Analysis)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
20MPA101T	Modern Pharmaceutical Analytical techniques	10	15	1 Hr	25	75	3 Hrs	100
20MPA102T	Advanced Pharmaceutical Analysis	10	15	1 Hr	25	75	3 Hrs	100
20MPA103T	Pharmaceutical Validation	10	15	1 Hr	25	75	3 Hrs	100
20MPA104T	Food Analysis	10	15	1 Hr	25	75	3 Hrs	100
20MPA105P	Pharmaceutical Analysis Practical-I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
20MPA201T	Advanced Instrumental Analysis	10	15	1 Hr	25	75	3 Hrs	100
20MPA202T	Modern Bio-Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
20MPA203T	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
20MPA204T	Herbal and Cosmetic Analysis	10	15	1 Hr	25	75	3 Hrs	100
20MPA205P	Pharmaceutical Analysis Practical-II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

11.2 Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table VII: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	**Maximum Marks**
Attendance (Refer Table– 30)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table– 30)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	**20**

Table VIII: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

11.2.1. Sessional Exams

Two Sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given below.

The average marks of two Sessional exams shall be computed for internal assessment as per the Requirements given in tables – X.

12. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M.Pharm programme if he/she secures at least 50% marks in that particular course including internal assessment.

13. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

14. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

15. Re-examination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table XIII. The exact dates of examinations shall be notified from time to time.

Table IX:Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and III	November / December	May / June
II and IV	May / June	November / December

16. Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and IIsemesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

17. Grading of performances

17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table –10.

Table X: Letter grades and grade points equivalent to Percentage of marks and performances

Letter Grade	Marks Range	Grade Point	Description
O	91 – 100	10	OUTSTANDING
A+	81 – 90	9	EXCELLENT
A	71-80	8	VERY GOOD
B+	66-70	7	GOOD
B	61-65	6	ABOVE AVERAGE
C	55-60	5	AVERAGE
D	50-54	4	PASS
RA	<50	0	REAPPEARANCE
AB	-	0	ABSENT

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 * \text{ZERO}}{C_1 + C_2 + C_3 + C_4}$$

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed statusin case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passedby obtaining a pass grade on subsequent examination(s) theCGPA shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

$$\textbf{CGPA} = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{\mathbf{C_1 + C_2 + C_3 + C_4}}$$

where $C_1, C_2, C_3, \ldots$ is the total number of credits for semester I,II,III,…. and $S_1, S_2, S_3, \ldots$ is the SGPA of semester I,II,III,…..

20. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction	=	8 and above
First Class	=	6.50 to 7.99
Second Class	=	5.00 to 6.49

21. Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages). The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks
Total	500 Marks

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks
Total	250 Marks

22. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

23. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

24. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

25. Revaluation I Retotaling of answer papers

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

26. Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

FACULTY OF PHARMACY

PG PROGRAM (CBSS) – M.PHARM

(2020–2021 Batch and onwards)

Course code	Name of the course	Objectives and out comes		Instruction hours / week			Credit(s)	Maximum Marks		
		PEOs	POs	L	T	P		CIA	ESE	Total
								25	75	100
SEMESTER - I										
20MPA101T	Modern Pharmaceutical Analytical Techniques	1,2	a,c,d,h,j	4	-	-	4	25	75	100
20MPA102T	Advanced Pharmaceutical Analysis	1,2	a,c,d,h,i,j	4	-	-	4	25	75	100
20MPA103T	Pharmaceutical Validation	1,2	a,d,h,j	4	-	-	4	25	75	100
20MPA104T	Food Analysis	1,2,3	a,b,h,i	4	-	-	4	25	75	100
20MPA105P	Pharmaceutical Analysis Practical I	1,2,4	a,b,c,d,h,I,j	-	-	12	6	50	100	150
-	Seminar/Assignment	-	-	7	-	-	4	-	-	100
Semester Total				**23**	**-**	**12**	**26**	**150**	**400**	**650**
SEMESTER – II										
20MPA201T	Advanced Instrumental Analysis	1,2,4	a,b,c,d,h,i,j	4	-	-	4	25	75	100
20MPA202T	Modern Bio-Analytical Techniques	1,2	a,b,c,d,h,i,j	4	-	-	4	25	75	100
20MPA203T	Quality Control and Quality Assurance	1,2	a,d,f,h,j	4	-	-	4	25	75	100
20MPA204T	Herbal and Cosmetic analysis	1,2	a,b,c,d,f,h,j	4	-	-	4	25	75	100
20MPA205P	Pharmaceutical Analysis Practical II	1,2,4	a,b,c,d,j	-	-	12	6	50	100	150
-	Seminar/Assignment	-	-	7	-	-	4	-	-	100
Semester Total				**23**	**-**	**12**	**26**	**150**	**400**	**650**
SEMESTER - III										
20MPA301T	Research Methodology and Biostatistics*	2,5	b,c,j	4	-	-	4	25	75	100
-	Journal club	-	-	1	-	-	1	25	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	2	-	-	2	50	-	50
-	Research Work	1,2,3,4,5	a,b,c,d,e,f,g,h,i,j	28	-	-	14	-	350	350
Semester Total				**35**	**-**	**-**	**21**	**100**	**425**	**525**
SEMESTER – IV										
-	Journal club	-	-	1	-	-	1	25	-	25
-	Research work	1,2,3,4,5	a,b,c,d,e,f,g,h,i,j	31	-	-	16	75	-	75
-	Discussion / Final Presentation	-	-	3	-	-	3	-	400	400
Semester Total				**35**	**-**	**-**	**20**	**100**	**400**	**500**

* Non-University Exam

PROGRAMME OUTCOMES (PO)

a. **Pharmacy Knowledge:** Demonstrate knowledge of the basic pharmaceutical sciences and the ability to acquire, manage and use current information for problem solving. Describe the synthesis, formulation, analysis, pharmacological, pharmacognostical, biotechnological and regulatory aspects of drugs and biopharmaceuticals. Identify the rules and regulations involved in the drug discovery and development, manufacture, distribution and sale of medicines.

b. **Planning Abilities:** Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines using modern tools.

c. **Research:** An ability to independently carry out research /investigation and development work to solve practical problems. Apply critical thinking skills, including investigation, application, analysis, creativity, evaluation of information, data and documents related to research investigation.

d. **Problem analysis:**Develop problem-based learning approach and analytical thinking in his/her academic and professional life. Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.

e. **Leadership qualities:** Demonstrate the ability to plan and implement professional activities. Act efficiently as a leader in the diverse areas of the profession.

f. **Communication Skills:** Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions. Imbibe the skills of scientific communication and research writing.

g. **The Pharmacist and society:**Apply the knowledge and skills gained through education to gain recognition in professional circle and society. Participate in healthcare initiatives to create awareness in society about the effective and safe use of medicines.

h. **Professional Ethics:**Exercise ethical practices and moral values in personal and professional endeavors. Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.

i. **Environment and sustainability:** Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.

j. **Life-long learning:**Tackle professional challenges through lifelong learning attitude. Work in a team and participate in lifelong learning and continuous improvement in the profession.

PROGRAMME SPECIFIC OUTCOMES (PSOs)

PSO k: Understand a core and basic knowledge in different subjects of Pharmaceutical Sciences. To prepare graduate to success in technical or professional careers in various pharmaceutical industry and/ or institute and /or Health care system through excellent real time exposure to rigorous education.

PSO l: Analyse the relationships among Pharmaceutics, Pharmaceutical and Medicinal Chemistry, Pharmacology and Pharmacognosy subjects. Understand the applications of Pharmaceutical Sciences in drug and formulation development, drug analysis, drug safety and efficacy in medicine.

PSO m: Perform procedures as per laboratory standards in the areas of Pharmaceutical Sciences.

PSO n: To strengthen the professional and ethical attitude, effective communication skills, teamwork skills, multidisciplinary approach, and an ability to relate pharmaceutical sciences issues to broader social context.

PSO o: To streams a lifelong career of personal and practicing professional growth with ethical codes and self-esteem for a highly productive career and to relate the concepts of Pharmaceutical Sciences towards serving the cause of the society.

PROGRAMME EDUCATIONAL OBJECTIVES (PEOs)

PEO 1

To provide a comprehensive and advanced pharmaceutical education leading to M. Pharm. Degree.

PEO 2

To integrate pharmacy knowledge and skills with pharmaceutical research.

PEO 3

To develop pharmacists to contribute effectively in the social health care system.

PEO 4

To provide hands on training through state of art infrastructure to inculcate research aptitude in pharmaceutical sciences.

PEO 5

To inculcate leadership and entrepreneurship capabilities in future pharmacy professionals.

MAPPING

PO	a	b	c	d	e	f	g	h	i	j	PSO k	PSO l	PSO m	PSO n	PSO o
PEO 1	X						X	X		X	X	X	X	X	
PEO 2	X	X	X	X		X		X		X	X	X	X	X	X
PEO 3	X	X		X		X	X	X	X	X	X	X		X	X
PEO 4	X	X	X	X						X	X	X	X	X	X
PEO 5	X	X	X	X	X	X		X	X	X				X	X

M.PHARM PHARMACEUTICAL ANALYSIS (MPA)

20MPA101T FIRST SEMESTER

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES 4H 4C

Instruction hours/ week: L: 4T:0P:0 Marks: Internal: 25 External: 75 Total:100
External Semester Exam: 3Hours

Course Objectives:

- This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs.
- The students will be dealing with instruments like NMR, Mass spectrometer, IR, HPLC, GC etc.
- Acquire skills in selecting the suitable techniques for analysis of drugs
- Validate the instruments used in pharma industry
- Expand the theoretical knowledge on various instrumental techniques available for analysis of organic substances
- Expertise in various spectroscopic studies

Course Outcome:

After completion of course student will

1. Persuade the theoretical and practical skills of the instruments
2. Analyze various drugs in single and combination dosage forms
3. Acquire skills in selecting the suitable techniques for analysis of drugs
4. Validate the instruments used in pharma industry
5. Expand the theoretical knowledge on various instrumental techniques available for analysis of organic substances
6. Expertise in various spectroscopic studies

THEORY **60Hrs**

1. a. UV-Visible spectroscopy: **10Hrs**

Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.

b. IR spectroscopy:

Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibration frequencies and Applications of IR spectroscopy, Data Interpretation.

c. Spectro flourimetry:

Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy:

Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy: 10Hrs

Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

3. Mass Spectroscopy: 10Hrs

Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

4. Chromatography: 10Hrs

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a. Thin Layer chromatography b. High Performance Thin Layer Chromatography c. Ion exchange chromatography d. Column chromatography e. Gas chromatography f. High Performance Liquid chromatography g. Ultra High Performance Liquid chromatography h. Affinity chromatography i. Gel Chromatography.

5. a.Electrophoresis: 10Hrs

Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

b. X ray Crystallography:

Production of X rays, Different X ray methods, Bragg‘s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

6. Potentiometry: 10Hrs

Principle, working, Ion selective Electrodes and Application of potentiometry. Thermal Techniques:

Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs),

Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

Reference Books (Latest Editions):

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons,2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore,1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi,1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS,1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi,1997.

7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. DekkerSeries

8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd.,Delhi.

9. Textbook of Pharmaceutical Analysis,KA.Connors, 3rd Edition, John Wiley & Sons,1982

20MPA102T FIRST SEMESTER

ADVANCED PHARMACEUTICAL ANALYSIS **4H 4C**

Instruction hours/ week: L: 4T:0P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3Hours

Course Objectives:

- This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities.
- The student will expertise in Impurity profiling and characterization of degradants,
- This subject deals with Stability testing of phytopharmaceuticals and their protocol preparation.
- It also covers the biological testing of various vaccines and their principle and procedure.
- The subject emphasize on assay and different tests for drug products.
- The subject also provides knowledge regarding immunoassay and techniques involved in immunoassay

Course Outcome:

After completion of the course students will,

1. Develop appropriate analytical skills required for the analytical method development
2. Discover principles of various reagents used in functional group analysis that renders necessary support in research methodology
3. Demonstrates the applications of analytical principles in the practical related problems
4. Design the analysis of impurities in drugs and residual solvents
5. Expertise in stability testing and biological methods of purity determination
6. Acquire skills in identifying the impurities in combinational drugs

THEORY **60Hrs**

1. Impurity and stability studies: **10Hrs**

Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines

Impurities in new drug products:

Rationale for the reporting and control of degradation products, reporting degradation products content of Patches, listing of degradation products in specifications, qualification of degradation products

Impurities in residual solvents:

General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents

2.Elemental impurities: 10Hrs

Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C,H, N and S analysis

Stability testing protocols:

Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

3. Impurity profiling and degradants characterization: **10 Hrs**

Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradant characterization with special emphasis. Photo stability testing guidelines, ICH stability guidelines for biological products

4 .Stability testing of Phytopharmaceuticals: 10Hrs

Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

5. Biological tests and assays of the following: 10Hrs

A. Adsorbed Tetanus vaccine
B. Adsorbed Diphtheria vaccine
C. Human anti haemophilic vaccine
D. Rabies vaccine
E. Tetanus Antitoxin
F. Tetanus ntiserum
G. Oxytocin
H. Heparin sodiumIP
I. Antivenom. PCR, PCR studies for generegulation, instrumentation (Principle and Procedures)

6. Immunoassays(IA) 10Hrs

Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.

Reference Books (Latest Editions):

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J.Mendham, R. C. Denney,5th edition, ELBS,1991.

2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, NewDelhi, 1997.

3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons,1982.

4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition,Wiley – Interscience Publication,1961.

5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi,3rd Edition, CBSPublishers New Delhi, 1997.

6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B,Volume11, Marcel DekkerSeries.

7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBSPublishers, NewDelhi,1964.

8. Indian Pharmacopoeia Vol I , II & III 2007, 2010,2014.

9. Methods of sampling and microbiological examination of water, firstrevision,BIS

10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley &Sons.

11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20,Elsevier,2005

12. Analytical Profiles of drug substances and Excipients – Harry G Brittan,Volume 21 – 30, Elsevier,2005.

13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press,London.

14. ICH Guidelines for impurity profiles and stability studies.

20MPA103T FIRST SEMESTER

PHARMACEUTICAL VALIDATION 4H 4C

Instruction hours/ week: L:4T:0P:0 Marks: Internal: 25 External: 75 Total:100
External Semester Exam: 3Hours

Course Objectives:

- The main purpose of the subject is to understand about validation and how it can be applied to industry
- The subject aims to improve the quality of the products.
- The subject covers the complete information about validation, types, methodology and application.
- The student will receive a deep knowledge on intellectual property rights
- The subject provides an advanced knowledge on patents and its specifications
- Different techniques like TOT, IPP and social responsibilities to be followed will be discussed.

Course Outcome:

Upon completion of the subject student will

1. Explain the aspect of validation
2. Carry out validation of manufacturing processes
3. Apply the knowledge of validation to instruments and equipment's
4. Validate the manufacturing facilities
5. Revise the importance of patent and intellectual property rights.
6. Construct method validation as per ICH guidelines

THEORY **60Hrs**

12Hrs

1. Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan. Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.

12Hrs

2. Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

12Hrs

3. Validation of Utility systems: Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen. Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning n place (CIP).

12Hrs

4. Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP5.

. **12Hrs**

5. General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices

Reference Books (Latest Editions):

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rdEd., Marcel Dekker Inc.,N.Y.

2. The Theory & Practice of Industrial Pharmacy, 3rdedition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese PublishingHouse,Bombay.

3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.

4. Validation of Aseptic Pharmaceutical Processes, 2ndEdition, by Carleton &Agalloco, (MarcelDekker).

5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci.Series, Vol. 157,2ndEd., Marcel Dekker Inc.,N.Y.

6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance inthe Pharmaceutical, Medical Device, and Biotech Industries, Syed ImtiazHaider

7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, InterpharmPress

8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.Carlton (Ed.) and JamesAgalloco

(Ed.), Marcel Dekker, 2nd Ed.

9. Analytical Method validation and Instrument Performance Verification by Churg Chan, HeimanLam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

20MPA104T FIRST SEMESTER

FOOD ANALYSIS **4H** **4C**

Instruction hours/ week: L: 4T:0P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3Hours

Course Objectives:

- This course is designed to impart knowledge on analysis of food constituents
- This course is designed to impart knowledge on analysis of finished food products.
- The course includes application of instrumental analysis in the determination of pesticides in variety of food products.
- The subject deals with legislation regulations associated with food products
- The subject covers a wide knowledge on analytical techniques to be followed in the determination of food regulations
- The subject also emphasize on analysis of fermented products like wine, spirits etc

Course Outcome:

At completion of this course student will

1. Understand various analytical techniques in the determination of food constituents
2. Devise various analytical techniques in the determination of food additives
3. Create various analytical techniques in the determination of finished food products
4. Demonstrate various analytical techniques in the determination of pesticides in food
5. Review various analytical techniques in the determination of food regulations
6. Recognize various analytical techniques in the determination of food legislations

THEORY **60Hrs**

12Hrs

1. Carbohydrates – Chemistry & classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, crude fibre and application of food carbohydrates.

Proteins - Chemistry and classification of amino acids and proteins, Physico- Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins.

12Hrs

2.a. Lipids – Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods.

b. Vitamins – classification of vitamins, methods of analysis of vitamins, Principles of microbial assay and physiological significance of vitamins of B-series.

12Hrs

3. Food additives – Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.

   Pigments and synthetic dyes- Natural pigments their occurrence and characteristic properties, permitted synthetic Dyes, Non-Permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes

12Hrs

4. General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.

   Analysis of fermentation products like wine, spirits, beer and vinegar.

12Hrs

5. Pesticide analysis-Effects of pesticides insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organo chlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products.

   Legislation regulations of food products with special emphasis on BIS, Agmark and US-FDA

Reference Books (Latest Editions):

1. The chemical analysis of foods–David Pearson,Seventh edition,Churchill Livingstone,Edinburgh London,1976
2. Introduction to the Chemical analysis of foods–S.Nielsen,Jones&Bartlettpublishers,BostonLondon,1994.
3. Official methods of analysis of AOAC International, sixth edition, VolumeI&II, 1997.
4. Analysis of Food constituents–Multon, Wiley VCH.
5. Dr.William Horwitz, Official methods of analysis of AOAC International,18 th edition,2005.

20MPA105P FIRSTSEMESTER

PHARMACEUTICAL ANALYSIS PRACTICAL I 12H 6C

Instruction hours/ week: L: 0T:0P:12 Marks: Internal: 50 External: 100 Total:150

External Semester Exam: 3Hours

Course Objectives:

- To estimate the samples using analytical instruments.
- To perform assay of official drug samples using analytical intruments
- To determine the impurity profile of drugs.
- To separate the mixtures of sample using chromatographic techniques.
- To demonstrate HPLC.
- To demonstrate gas chromatography.

Course Outcome:

At completion of this course student will

1. Demonstrate the analysis of pharmacopieal compounds and simultaneous estimation by UV-VIS
2. Acquire skills in selecting the suitable techniques for analysis of drugs
3. Expertise in stability testing and biological methods of purity determination
4. Validate impurity profiling of drugs
5. Compare and contrast various methods of analysis and their outcomes
6. Demonstrate calibration of various glassware and instruments used in pharma industry

CONTENTS:

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multicomponent containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group

11. Colorimetric determination of drugs by using different reagents
12. Impurity profiling of drugs
13. Calibration of glassware's
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC any instrument
18. Calibration of HPLC instrument
19. Cleaning validation of anyone equipment
20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food product
28. Determination of density and specific gravity of foods
29. Determination of food additive

Reference Books (Latest Editions):

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons,2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore,1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi,1997.

5.Organic Spectroscopy - William Kemp, 3rd edition, ELBS,1991.

6.Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi,1997.

7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. DekkerSeries

8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd.,Delhi.

20MPA201T SECOND SEMESTER

ADVANCED INSTRUMENTAL ANALYSIS 4H 4C

Instruction hours/ week: L: 4T:0P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3Hours

Course Objectives:

- This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs.
- Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.
- The course provides an elaborate knowledge on HPLC in the field of nanotechnology and approaches for advancement in enantiomeric separations.
- The course offers advanced biochromatographical techniques, its approaches and derivatization.
- The subject includes hyphenation techniques in LC-MS and DART MS analysis
- 13C NMR, 1-D and 2-D NMR, NOESY and COSY techniques were also included in the study

Course Outcome:

After completion of course student will,

1. Interpret NMR, Mass and IR spectra of various organic compounds
2. Demonstrate theoretical and practical skills of the hyphenated instruments
3. Undergo Identification of organic compounds
4. Acquire Practical aspects and troubleshooting techniques for HPLC techniques
5. Expertise in controlling the parameters that affect drug manufacturing
6. Acquire Practical aspects and troubleshooting techniques for GC techniques

THEORY **60Hrs**

12Hrs

1.HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nanoliquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC,

practical aspects of preparative HPLC. **12Hrs**

2. **Biochromatography:** Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases. Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification. High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications. **12Hrs**

3. Super critical fluid chromatography: **Principles, instrumentation, pharmaceutical applications.**

Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis.CE-MS hyphenation. **12Hrs**

4. Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight,FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF;Q-IT, Q-TOF,LTQ-FT,LTQ-Orbitrap. **12Hrs**

5. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to 13CNMR:Spin spin and spin lattice relaxation phenomenon. 13C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy.LC-NMR hyphenations.

Reference Books (Latest Editions):

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, john Wiley & Sons,2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,TimothyA. Nieman, 5th edition, Eastern press, Bangalore,1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS,1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC- PD Sethi, CBS Publishers , New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,3rd Edition, CBS Publishers, New Delhi,1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, MarcelDekker Series.
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

20MPA202T SECOND SEMESTER

MODERN BIO-ANALYTICAL TECHNIQUES 4H 4C

Instruction hours/ week: L:4T:0P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3Hours

Course Objectives:

- This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.
- The subjects deals with different pharmacokinetic and pharmacodynamic parameters
- The subject emphasize on bioavailability and bioequivalence studies
- The course provides a detailed advancement on toxicokinetic studies and its importance in preclinical studies.
- The course outlines on cell culture techniques and its applications including MTT.
- The course provides knowledge on LC-MS in bioactivity screening and proteomics

Course Outcome:

Upon completion of the course, the student will

1. Undergo Extraction of drugs from biological samples
2. Demonstrate separation of drugs from biological samples using different techniques
3. Interpret the guidelines for BA/BE studies
4. Persuade a deep knowledge on BCS classification system and its applications in new drug discovery process
5. Understand various pharmacokinetics and Pharmacodynamic parameters affecting drug efficacy
6. Acquire knowledge on LC-MS in bioactivity screening and proteomics.

THEORY **60Hrs**

12Hrs

1. Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid -Liquid extraction and Solid phase extraction and other novel sample preparationapproach.

   Bioanalytical method validation: USFDA and EMEA guidelines.

12 hrs

2. Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution

Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability*: In-vitro*, *in-situ* and *In-vivo* methods.

12 hrs

3. Pharmacokinetics and Toxicokinetics: Basic consideration, Drug interaction (PK-PD interactions)

   The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450- based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics- Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies.LC-MS in bioactivity screening and proteomics.

12 rs

4. Cell culture techniques Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

12 rs

5. Metabolite identification: In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met –ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes.

   Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

Reference Books (Latest Editions):

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition.CRC Press, Newyork.1995.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,TimothyA. Nieman, 5thedition, Eastern press, Bangalore,1998.

3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2ndEdition,Wiley – Interscience Publications, 1961.

4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson,Volume 11, Marcel DekkerSeries

5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2ndEdition, John Wiley & Sons, New Jercy.USA.

6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2ndEdition, Marcel Dekker,Newyork,

USA. 1997.

7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA.2007.

8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series,1995.

9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.

10. ICH, USFDA & CDSCO Guidelines.

11. Palmer

20MPA203T SECOND SEMESTER

QUALITY CONTROL AND QUALITY ASSURANCE 4H 4C

Instruction hours/ week: L:4 T:0 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3Hours

Course Objectives:

- This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries.
- It covers the important aspects like cGMP,QCtests ,documentation ,quality certifications ,GLP and regulatory affairs.
- Procedures to ensure confidentiality of inventory and source category information, when required are explained
- Frequency of QA/QC checks on different parts of the inventory was dealt in the subject
- The subject covers about glp responsibilities nad regulatory affairs
- The subject deals with SOPs or standard operating procedures

Course Outcome:

At the completion of this subject it is expected that the student will,

1. Understand the cGMP aspects in a pharmaceutical industry
2. Appreciate the importance of documentation
3. Understand the scope of quality certifications applicable to Pharmaceutical industries
4. Recognize the responsibilities of QA & QC departments
5. Acquire knowledge on GLP and regulatory Affairs
6. Interpret CPCSEA guidelines

THEORY **60hrs**

1. Concept and Evolution of Quality Control and Quality Assurance Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. **12Hrs**

2. cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical

Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice .CPCSEA guidelines. **12Hrs**

3. Analysis of raw materials, finished products, packaging materials, in process quality control(IPQC), Developing specification (ICH Q6 and Q3) Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments,suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias Quality control test for containers, closures and secondary packing materials.

12 Hrs

4. Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc.

Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.

12Hrs

Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control sterile products, aseptic process control, packaging.

12Hrs

Reference Books (Latest Editions):

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, olume I & II, Mumbai,1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series,1995.
3. QualityAssuranceofPharmaceuticals-AcompediumofGuidelinesandRelatedmaterialsVolI&II,2nd edition, WHO Publications,1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra,1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva,2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.7. ICH guidelines
7. ISO 9000 and total quality management114
8. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, SusmitPublishers,2006.
9. QA Manual – D.H. Shah, 1st edition, Business Horizons,2000.
10. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig,Vol. 52, 3rd edition, Marcel Dekker Series. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
11. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons;2008.

20MPA204T SECOND SEMESTER

HERBAL AND COSMETIC ANALYSIS **4H 4C**

Instruction hours/ week: L: 4 T:0 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3Hours

Course Objectives:

- This course is designed to impart knowledge on analysis of herbal products.
- Regulatory requirements, herbal drug interaction with monographs were explained.
- Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.
- Describe guidelines for cGMP, GAP, GMP and GLP for quality assurance of herbal drugs in industry
- Describe guidelines for quality control of herbal drugs and evaluation of safety and efficacy of herbal medicines.
- The subject deals with herbal drug interactions

Course Outcome:

At completion of this course student will

1.Determine the herbal remedies and regulations

2.Demonstrate the analysis of natural products and monographs

3.Interpret Herbal drug-drug interaction

4.Exploit the principles of performance evaluation of cosmetic products.

5. Understand the pre requisites to be followed in the preparation of the herbal monographs

6. Express the Indian Standard specification laid down for sampling and testing of various cosmetics

THEORY **60Hrs**

1. Herbal remedies- Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO andAYUSHguidelines. **12Hrs**

2 .Adulteration and Deterioration: Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing

techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations. Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products anditsprotocol. **12Hrs**

3.Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products,protocol.

Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment ofherbaldrugs. **12Hrs**

4. Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety ofherbalmedicines. **12Hrs**

5. Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as perBIS.

Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the BureauIndianStandards. **12Hrs**

Reference Books (Latest Editions):

1. Pharmacognosy by Trease andEvans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO,Geneva
4. Pharmacognosy &Pharmacobiotechnology by AshutoshKar
5. Essential of Pharmacognosy byDr.S.H.Ansari
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P.Sharma, 4th edition, Vandana Publications Pvt. Ltd.,Delhi
7. Indian Standard specification, for raw materials, BIS, NewDelhi.
8. Indian Standard specification for 28 finished cosmetics BIS, NewDelhi

9. Harry's Cosmeticology 8th edition

10. Suppliers catalogue on specialized cosmeticexcipients

11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics andSoaps

12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition

20MPA205P SECOND SEMESTER

PHARMACEUTICAL ANALYSIS PRACTICAl II 12H 6C

Instruction hours/ week: L: 0T:0P:12 Marks: Internal: 50 External:100 Total:150

External Semester Exam: 3Hours

Course Objectives:

- To estimate the samples using analytical instruments.
- To perform the interpretation of organic compound by FTIR, NMR, MS etc
- To determine the impurity profile of drugs.
- To separate the mixtures of sample using chromatographic techniques.
- To demonstrate the protocol preparation and performance of bioanalytical method validation
- To demonstrate cosmetic analysis.

Course Outcome:

At completion of this course student will

1. Demonstrate the interpretation of various organic compounds by FT-IR
2. Demonstrate the interpretation of various organic compounds by NMR
3. Demonstrate the interpretation of various organic compounds by mass spectroscopy
4. Interpret Protocol preparation and performance of analytical/ Bioanalytical method validation
5. Formulate cosmetics and carry out its evaluation
6. Appreciate the importance of documentation by preparing master formula record, batch manufacturing records etc.

CONTENTS:

1. Comparison of absorption spectra by UV and Wood ward – Fiesurerule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.

8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/ Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. In process and finished product quality control tests for tablets, capsules, parenterals and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.
18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and Developer in hair dye
20. Determination of foam height and SLS content of Shampoo.
21. Determination of total fatty matter in creams (Soap, skin and hair creams)
22. Determination of acid value and saponification value.
23. Determination of calcium thioglycolate in depilatories

Reference Books (Latest Editions):

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons,2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore,1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi,1997.

5.Organic Spectroscopy - William Kemp, 3rd edition, ELBS,1991.

6.Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi,1997.

7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. DekkerSeries

8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd.,Delhi.

9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons,1982